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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/662,437	09/16/2003	Paola Minoprio	03495-0200-02	2639

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FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP
901 NEW YORK AVENUE, NW
WASHINGTON, DC 20001-4413

EXAMINER	
FORD, VANESSA L	
ART UNIT	**PAPER NUMBER**
1645	

DATE MAILED: 09/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/662,437	MINOPRIO ET AL.	
	Examiner	Art Unit	
	Vanessa L. Ford	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 August 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *79-85 and 87-109* is/are pending in the application.

4a) Of the above claim(s) *81,82,84,85,87-89 and 91-100* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *79,80,83 and 90* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *9/16/2005* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *1/7/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. This Office action is responsive to Applicant's response to the restriction requirement mailed August 23, 2005. Applicant elected Group I, claims 79, 80, 83, 86 and 90 and SEQ ID NO: 8 to be examined in this application. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Applicant's amendment is acknowledged. Claim 79 has been amended. Claims 1-78 and 86 have been cancelled. Claims 81-82, 85, 87-89, 91-109 have been withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Specification

2. The substitute specification filed September 16, 2003 has not been entered because it does not conform to 37 CFR 1.125(b) and (c) because: The substitute specification must be submitted with markings showing all the changes relative to the immediate prior version of the specification of record. The text of any added subject matter must be shown by underlining the added text. The text of any deleted matter must be shown by strike-through except that double brackets placed before and after the deleted characters may be used to show deletion of five or fewer consecutive characters. The text of any deleted subject matter must be shown by being placed within double brackets if strike-through cannot be easily perceived. An accompanying clean version (without markings) and a statement that the substitute specification contains no new matter must also be supplied. Numbering the paragraphs of the

specification of record is not considered a change that must be shown. A substitute specification must not contain new matter.

Claim Objection

3. Claims 79-80, 83 and 90 are objected to for the following informality: The claims should be the subject of a complete sentence and the claims should also state "What is claimed is ..." or "We claim ..." Correction is required.

4. Claim 80 is objected to for the following informality: "a" should be changed to "the" on line 2 of this claim. Correction is required.

Drawings

5. The Drawings are objected to for the following reasons: The figures should correspond to the text as set forth in the Brief Description of the Drawings. For example, Figure 5 should recite "Figure 5A" and "Figure 5B" in the Brief Description of the Drawings and so forth. It should be also noted that sequences on pages 86-96 have not been identified in the instant specification. Correction and/or clarification is requested.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 79-80 and 83 are provisionally rejected under the judicially created doctrine of double patenting over claim 1 of copending Application No. 10/427925 filed May 2, 2003. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

Claims 79-80 and 83 of this application are directed to a purified nucleic acid molecule comprising the sequence of SEQ ID NO:8. and claim 1 of the co-pending application 10/427925, is directed to a purified nucleic acid molecule selected from the group consisting of SEQ ID NOs: 7, 8, 9, 10 and 11.

Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 1 (as it relates to SEQ ID NO:8) of co-pending

application no. 10/427925 would be a species of the nucleic acid molecules that are encompassed by the genus of nucleic acid molecules claimed in this application.

For art purposes, the Examiner is interpreting claims 80 and 83 as being directed to any recombinant vector and host cell since the recombinant vector only directs expression of "a" nucleic acid molecule of claim 79 and the claims do not recite that the claimed DNA is contained in the vector. For art purposes, the Examiner is interpreting claim 90 as being directed to any polynucleotide, which hybridizes to the molecule of claim 79 and reagents to perform a nucleic acid hybridization reaction.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 80 and 83 are rejected under 35 U.S.C 102(b) as anticipated by Cordeiro da Silva et al *(Immunology 1998, 94, 189-196).*

Claims 80 and 83 are drawn recombinant vector that directs the expression a nucleic acid molecule of claim 79 and a host cell transfected or transduced with the recombinant vector of claim 80.

Cordeiro da Silva et al teach a high-expression vector, PGEX-2 plasmid that directs synthesis of polypeptides in *E. coli* (host cell)(page 190). Cordeiro da Silva et al

teach that a trypomastigote cDNA was subcloned into the pGEX-2 plasmid (page 190). Cordeiro da Silva et al anticipate the claimed invention.

Since the Office does not have the facilities for examining and comparing applicant's vector and host cell with the vector and host cell of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the vector and host cell of the prior art does not possess the same material structural and functional characteristics of the claimed vector and host cell). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

8. Claim 90 is rejected under 35 U.S.C 102(b) as anticipated by STRATAGENE, *(Prime-It™kit , 1991).*

Claim 90 is drawn to a kit for detecting a parasite, said kit comprising a polynucleotide probe which hybridizes with the nucleic acid molecule of claim 79 and reagents to perform a nucleic acid hybridization reaction.

STRATAGENE teaches a kit (The PRIME-It™) comprising a T7 DNA polymerase, dilution buffer, reaction buffers, stop mix (reagents to perform hybridization reactions) and random 9mer primers (polynucleotide probes) which can hybridize to the claimed nucleic acid molecule. The claim limitation " for detecting a parasite" is being viewed as a limitation of intended use. STRATAGENE anticipates the claimed invention.

Since the Office does not have the facilities for examining and comparing applicant's kit with the kit of the prior art, the burden is on the applicant to show a novel

or unobvious difference between the claimed product and the product of the prior art (i.e., that the kit of the prior art does not possess the same material structural and functional characteristics of the claimed kit). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

9. Claims 79-80, 83 and 90 are rejected under 35 U.S.C 102(b) as anticipated by the Billaut-Mulot et al *(Biol. Cell, 1994, 82(1):39-44)(Abstract only).*

Claims 79-80, 83 and 90 are drawn to a purified nucleic acid molecule comprising the sequence of SEQ ID No:8 vector, host cell comprising the purified nucleic acid molecule and a polynucleotide probe that hybridizes to the molecule of claim 79.

Billaut-Mulot et al et al teach a *Trypanosoma cruzi* cDNA clone corresponding to the *Trypanosoma cruzi* 45 kDa protein (see the Abstract). Billaut-Mulot et al et al teach that the trypomastigote cDNA insert was purified and subcloned into a vector (see the Abstract). Billaut-Mulot et al et al teach that the vector was expressed in *Escherichia coli* (see the Abstract). Billaut-Mulot et al et al teach that random primed cDNA hybridized to with a single 1.4 kb mRNA found in epimastigote, trypomastigote and amastigote forms. Billaut-Mulot et al et al teach that southern blot analysis were performed (see the Abstract). Therefore, the prior art teaches DNA that are can hybridize to a purified nucleic acid molecule that comprises that the nucleic acid sequence as set forth in SEQ ID NO:8. The reagents that are use in hybridization reactions are inherent in the teachings of the prior art. The nucleic acid sequence as is

set forth in SEQ ID NO:8 would be inherent in the teachings of the prior art. The term "kit" constitutes an "intended use". Intended use does not impart patentable weight to a product. See MPEP 2111.03: Intended use recitations and other types of functional language cannot be entirely disregarded. However, in apparatus, article, and composition claims, intended use must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. In re Casey, 370 F.2d 576, 152 USPQ 235 (CCPA 1967); In re Otto, 312 F.2d 937, 938, 136 USPQ 458, 459 (CCPA 1963). Billaut-Mulot et al anticipate the claimed invention.

Since the Office does not have the facilities for examining and comparing applicant's nucleic acid molecule with the nucleic acid molecule of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the nucleic acid molecule of the prior art does not possess the same material structural and functional characteristics of the claimed nucleic acid molecule). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Pertinent Prior Art

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure *(Verdun et al, Infection and Immunity, November 1998, p. 5393-5398).*

Status of Claims

11. No claims are allowed.

Conclusion

12. Any inquiry of the general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308–0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Office Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for the Group 1600 is (703) 872-9306.

Any inquiry concerning this communication from the examiner should be directed to Vanessa L. Ford, whose telephone number is (571) 272-0857. The examiner can normally be reached on Monday – Friday from 9:00 AM to 6:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached at (571) 272-0864.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov./>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Vanessa L. Ford
Biotechnology Patent Examiner
September 8, 2005

LYNETTE R. F. SMITH
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600